

Clinical aspects and medico legal issue in patients with Alzheimer's disease, what is an ethical approach to care?

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Abstract

Dementia are a class of disease based on several etiological factors, clinical pattern, the most common is the Alzheimer's disease, followed by the vascular form or mixed (vascular-degenerative), by dementia at Lewy body and by frontotemporal dementia.

In Italy the number of people with dementia estimated is about one million of which about the 60%-70% is affected by Alzheimer's disease.

Dementia causes a progressive loss of autonomy and burdensome burden of care, not only from the emotional point of view, but organizational for both family members and health care workers.

The assessment of the person's abilities, with dementia presenting anosognosia, requires not only a careful assessment, but also an approach to support interventions in the various areas relating to the management of daily life, financial and patrimonial choices, as well as the definition of the therapeutic and care plan.

This document examine the reference models, useful for the purpose of an assessment of ability and skills of the patient affected by Alzheimer dementia.

It also reviews regulatory provisions that influence clinical management choices.

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Introduction

In the European Union physicians have a legal obligation to obtain consent before treating a patient, and in some countries this obligation applies to clinical research.

Informed consent represents an autonomous decision made by a competent person who, after being fully informed about the study, the treatment, the alternatives, having understood

the information provided and being capable of making a decision on the basis of the information received and the risks associated to the therapy, freely agrees to participate in that study.

Giving informed consent is a complex process requiring cognitive skills. Alzheimer's disease gradually progresses, making informed consent difficult or even impossible to obtain in some cases.

One of the issues that must be taken into account for clinical research and healthcare involving patients with dementia concerns their cognitive impairment and poor judgment. These aspects are present during the progression of the disease and can impair their capacity to make informed decisions. Several approaches have been recommended for assessing this capacity.

The guidelines approved by the American Psychiatric Association in 1997 [1], indicate four “abilities” for assessing whether the individuals are able to make decisions:

- The ability to evidence a choice;
- The ability to understand relevant information;
- The ability to appreciate the situation and its consequences;
- The ability to manipulate information rationally.

The Italian Medicine Agency (AIFA) resolution of 28 December 2006 [2] raises the issue of the consent of patients with dementia in relation to the off-label prescription of anti-psychotic medications.

Caregivers face significant difficulties when dealing with mental and behavioural disorders in patients with dementia and these disorders are often the main reason for emergency medical services or urgent visits in medical practices. However, their treatment requires a pharmacological intervention subject to the same requirements as any non-compulsory medical treatment pursuant to specific legal provisions.

Pharmacological treatment of patients with Alzheimer’s disease is subject to the constitutional principle according to which “(...) *no one may be obliged to undergo any given health treatment (...)*” (article 32 of the Constitution of the Italian Republic) [3].

Information necessary to make the personal consent valid is therefore needed prior to any medical procedure.

Medical specialists working in Alzheimer’s disease Memory Clinic often deal with patients showing serious cognitive and behavioural disorders, and almost always these patients do not have a legal representative (i.e., they are not interdicted) or a health-care agent.

In the case of an incapacitated patient with behavioural disorders and needing urgent treatment using medications able to control these disorders, with the patient not having any legal representatives, the doctor must take action according to articles 36 (Urgent medical assistance) and 37 (Consent given by the legal representative) of the Italian Code of Medical Ethics [4].

Art. 36 of the Italian Code of Medical Ethics states that “Where there are conditions of urgency, the clinician should take steps to ensure vital assistance, taking into account the willingness of the person, when expressed”. Art. 37 states that “...if the life of a minor or incapacitated person is threatened or there is a serious risk to the health of a minor or incapacitated person, the clinician must in any case proceed without delay and as necessary to the treatment needed”.

Amongst neurodegenerative disorders, Alzheimer’s disease is one of the most serious. It is desirable that patients are taken care of by a health-care agent for the entire course of the treatment, not just for the administration of atypical antipsychotics.

Awareness in alzheimer’s disease

Research conducted up to now shows that awareness is maintained in the early stages of the Alzheimer’s disease, compromised at various levels in the intermediate stages and lacking in the late stages [5,6].

The term anosognosia, awareness insight are however now used to indicate awareness of the symptoms and/or of the disease in general.

Lack of awareness is present in a different way in all forms of dementia, this data therefore confirms that the degree of awareness is generally linked to severity in Alzheimer’s disease [7-9].

Dementia at an early stages

In early-stage dementias, insight is preserved, memory is slightly impaired, with a fair understanding of Simple Discourses [10].

Dementia in advanced stage (CDR>3)

In the advanced stages the patient often, but not always, has a diminished awareness and is not perfectly able to understand the diagnosis and the possible evolution.

In literature skills and competence are often used interchangeably, although they are not overlapping (e.g. clinical and legal field), and with important differences in Anglo-Saxon literature compared to ours.

It is essential to make a distinction between the assessment of cognitive abilities and behavioural disorders that can undermine the patient’s ability with respect to the legal determination of his (in) ability.

Clinical evaluation alone is not an inability of the patient [11]. The latter, even if it is expressed by experts (doctors, psychologists, neuropsychologists), represents the outcome of a judicial procedure that is entirely up to the judge. At the clinical level the ‘capacity’ also defined competence - includes all individual skills that allow the person to perform actions from the most elementary of daily life to more complex choices that can have consequences at the economic or health level.

The evaluation of these abilities is the clinician who will provide his own assessments, which will allow the judge to decide on the legal capacity of the person [12,13].

The term ability in jurisprudence, identifies something that distinguishes a person who can make a decision and whose choice must therefore be respected (regardless of the reasonableness of that decision), by the person who needs others to decide for him” [14].

In assessing a person’s ability, it is necessary to consider, in addition to his ability.

Decision-making and cognitive fitness, including the type of task required by the particular circumstances.

In healthcare, assessment of the patient’s ability to give informed consent to the medical act (e.g. decide to undergo an operation surgical procedure, to an invasive diagnostic procedure), ability that can remain intact even in a person who is no longer considered capable of administering their finances.

It follows that the ability to decide does not simply depend

on the ability of the patient, but the coincidence or not between its abilities and the specific demands of the environment, the capacity assessment cannot be based only on the examination of functional skills but also on the contingent demands.

The judgment of incapacity can lead to a significant reduction of the rights of the individual, and are considered a particularly sensitive field of investigation [15].

At the same time, not recognising a decrease in the level of capacity can cause different risks for the person with dementia and for other people (e.g. deception or fraud, failure to plan and request support actions, etc.) therefore, the decision to propose specific capacity assessments in response to a request from the family member, MMG, CDCD specialist or judge, must be made taking into account the context in which the person lives, the resources he has available (family and economic) and the different risks and benefits that would derive to the person and his family members from leaving things unchanged with respect to setting up one or more support measures.

The variability of the contingencies makes it appropriate to have an evaluation protocol to be applied in a flexible form, but sufficiently complete to be neither too focused on particular aspects nor lacking in relevant information.

Capacity and awareness at different stages of disease

To date in Italy we do not have a “gold standard” tool to ‘measure’ the capacity, nor guidelines proper. In daily practice, judgment is often based on clinical observation, supplemented by the result of psychodiagnostic evaluation.

In the USA, ad hoc assessment scales have been proposed and used (not yet validated in Italian) which, however, if separated from a competent clinical and neuropsychological evaluation, may prove unreliable.

The traditional tools of neuropsychological investigation must be integrated to a careful functional evaluation of what the subject is actually able to do.

A clinical assessment of abilities requires a multidimensional approach and the clinician who must give a judgment on the ability of a person, must have the highest professional competence, and a broad knowledge of the neuropsychological investigation tools to be applied in the different stages of disease progression [16].

In the early stages of illness, management skills are involved for tasks with a higher cognitive content and at the same time the ability to adapt to various social situations.

In the mild stage the person may still be capable enough to decide where he wants to live, but not be able to decide which investments to make; he may be able to choose between two different medical treatments, but not be able to decide whether to take or fewer life-saving therapies needed.

The progressive impairment of capacity also varies according to the type of dementia [17]. Capacity is not separated from another function also involved in the degenerative process, awareness, the definition of which involves other cognitive aspects such as “anosognosia” (lack of awareness of symptoms) and “awareness” (awareness of memory deficits, language, visuo-perceptive functions).

There are several aspects of awareness: awareness of an ongoing change, awareness of a specific symptom (such as mem-

ory disorder), awareness of having a disease. Most of the works of the literature examine the awareness of neuropsychological deficits (memory, executive functions, etc.), less attention is paid to the functional state and behavioral disorders.

Tools for cognitive evaluation

Clinical observation and psychodiagnostic evaluation are of fundamental importance for the framing and monitoring of capacity. Some of the most frequently used neuropsychological tests validated in the Italian population are: The awareness questionnaire (Awareness Questionnaire for Dementia [18-20]).

There are many abilities of the patient with dementia, which the clinician can be called to examine with medical-legal purposes: the ability to allow treatment, to testify, to make wills, to manage their finances, to hold and use a weapon, to carry out a profession, etc. being able to act these activities, in addition to requiring the suitability for the task, requires the maintenance of a decision-making capacity, which can be compromised by diseases of various kinds, neurological or psychiatric.

In both clinical and legal areas, the ability can be preserved in individual areas, the subject may have the ability to consent to treatments but at the same time may have lost the ability to negotiate.

For this reason, setting minimum or maximum thresholds, through MMSE, MOCA or other tests and defining flow charts may appear arbitrary and risky, even considering the different ways in which the various types of dementia occur.

It would be appropriate to outline the limits of cognitive performance in order to offer a reference point, not binding, for a better classification of the subjects to be submitted subsequently to the judgment of competence.

Cognitive deficits represent strong predictors of decision making in healthcare: episodic memory, naming, working memory and functions executive. Recent studies have also shown that increased intra-individual variability in performance can be predictive of a higher risk of decision-making incapacity [21]. Informed consent encounters difficulties, although it is relatively easy to apply, in the absence of the preconditions provided by the framework developed by Beauchamp and Childress [22]: Correctly given information, i.e. information from the clinician’s point of view.

Properly understood information, i.e. information from the patients’ point of view, with their ability to understand the information given and integrate them into the awareness of their overall condition.

Freedom, i.e. freedom to decide in the absence of conditioning factors or at least being aware of their presence.

Ability to decide. This element is the ability addressed in this work.

Patients in the early stages of the disease are aware of their memory problems. Many studies have analysed the relation between awareness and psychical symptoms. According to some studies, high degrees of awareness would be related to a higher risk of depression [23]. Apathy would be related to a lower level of awareness of the disease [24]. Psychotic symptoms and loss of awareness are often present in the late stages of dementia and appear to be caused by a dysfunction of the frontal cortex and of the relevant subcortical structures [25].

Problems relating to awareness are often connected to issues relating to diagnosis and prognosis given to patients and their family members [26].

Communicating the diagnosis to patients allows to comply with one of the key principles in biomedical ethics, the respect for autonomy, that is the person's right to make decisions on the proposed health treatment.

The Italian National Bioethics Committee (2014) [27] acknowledged that the decision-making capacity in patients with Alzheimer's disease must be assessed during the relevant stage of the disease and in relation to the decision to make. Moreover, it stated that research in the field of neuropsychiatry must define protocols assessing the functional aspects underlying the decision-making, in order to involve the patient as far as possible in the treatment and care decisions. There are several appropriate legal instruments in order to protect individuals with dementia, given that the disease gradually impairs judgment. These instruments aim to protect the patient's life and financial rights and interests.

Assessment of the ability to make treatment decisions and to give consent

The Oviedo Convention (1997) [28] and the Italian Code of Medical Ethics (2014) [4] laid down the principle of autonomy in making treatment choices. Dementia is characterized by a progressive loss of the abilities autonomy is based on. Moreover, there is a lack of awareness of the disease and of its symptoms (cognitive impairment, behavioural disorders, alterations in the functional status).

The Bioethics and Palliative Care in Neurology Study Group of the Italian Society of Neurology and of the Italian National Institute of Health [29,30] have examined the question coming to appreciate that the evaluation of a patient with dementia and BPSD, aiming to assess the ability to give treatment consent, should include a clinical/anamnestic assessment, a neuropsychological assessment and an evaluation of the patient's perception of the disease state and ability to make decision. This evaluation should particularly focus on the ability to understand relevant information, assess the meaning of the information received regarding their personal conditions, consider the significant information in order to compare risk and benefits of the different proposed alternatives and make a choice.

Informed consent and abilities relating to the capacity to make decisions

Informed consent is the basic prerequisite of every medical procedure. Autonomy refers to the respect for fundamental human rights, including the right to self-determination, and it allows patients who are fully capable to make decisions on medical care and any therapeutic treatment. The patient's autonomy.

In addition to information (properly given and understood) and freedom (absence of conditioning factors or at least awareness of their presence), the capacity to make decisions is a precondition for informed consent.

The capacity to make treatment decisions is inherent in the legal concept of legal capacity (art. 2 of the Italian Civil Code).

The definition proposed by Wong et al. [31] provides an indication of the relationship between the person's capacity and the society surrounding him: "Capacity" distinguishes the

person who is capable of making a decision and whose choice must, therefore, be respected, from one who requires others to make decisions for him or her". This is a clinical definition and differs from the legal definition of "competence".

There are cases where a person may not be able to manage his/her current account but can still give his/her consent to a simple medical treatment. The capacity to make decisions must be assumed to be present until proven otherwise. Thus dementia is a risk factor for incapacity, but it does not necessarily imply incapacity. (In) capacity is always related to a specific task. For example, a person can be able to make a decision on a simple medical treatment and at the same time can be unable to consider complex alternatives with several risk/benefit profiles.

"Clinical competence" refers to self-determination in the field of health care [32]. The capacity to make decisions is made up of the parameters laid down in 1977 and later reviewed [33,34].

The parameters refer to:

Ability to evidence a choice;

Ability to understand the information relating to a choice;

Awareness of the importance of a choice and its consequences;

Reasoning and logic skills, e.g. being able to focus on a problem, develop solutions and understand its likely consequences.

In Alzheimer's disease there would be a relationship between capacity and cognitive level (MMSE) and between capacity and neuropsychological deficits, in relation to semantic memory and executive functions [35].

The conflict between freedom of treatment and protection is obvious. Therefore, in order to avoid any "paternalistic" approaches it is necessary to appoint a legal representative, i.e. a health-care agent, as the only viable alternative [36]. The analysis of the literature concerning the evaluation of capacity shows an absence of diagnostic measures designed ad hoc for the various types of capacity, calibrated in the Italian population. This aspect causes a serious limitation to the work of the specialist doctor, neurologist and/or geriatrician who draws the profile of each capacity through indirect measures.

Assessment of abilities, in all its facets, implies a multidimensional approach and the clinician called upon to give a judgment on the ability of a person must guarantee a wide knowledge of the tools of neuropsychological investigation and especially of the limits indicated in the previous paragraphs. To be consistent with this objective, the ideal capacity assessment path should include:

A detailed history with the subject to be examined and all those who can give information (family, friends, colleagues, doctor);

A battery of neuropsychological tests with validated tests, exploring both the general cognitive state, and those cognitive functions whose integrity is deemed indispensable for that single capacity;

An assessment of skills related to individual capacity, including the use of tools that allow an environmentally sound representation of individual capacity;

Interpretation of pathology-related findings (clinical fea-

tures, course),

Legal reference standards (for example legal thresholds for informed consent in dementia) [37-40].

The need to protect the population of patients suffering from Alzheimer's dementia is hoped to prompt the activation of working groups for the creation and standardization of tools valid for the Italian population.

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